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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,110	03/30/2001	Hwa-Chain Robert Wang	4350.000800	9178

7590 11/23/2001

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EXAMINER
JAMROZ, MARGARET E

ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/822,110	Applicant(s) WANG, HWA-CHAIN ROBERT	
	Examiner Margaret E Jamroz	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *restriction election facsimile* .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz in Art Unit 1644, Group 1640, Technology center 1600.

Sequence Compliance

2. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

3. The following is noted:

Claims 1-60 encompass compositions, kits, cells, methods of detecting, methods of generating, and methods of inhibiting that utilize different products: native, or biologically active, or denatured $p33^{QIK}$ or $p63^{Krs1}$ peptides or polypeptides. $p63^{Krs1}$ and $p33^{QIK}$ differ with respect to their structure, a person of ordinary skill in the art would not envision one in view of the other. In addition, they differ in mode of action. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

Claims 13-60 encompass antibodies that recognize an isolated peptide (any of SEQ ID NOS: 3-76), a polypeptide consisting essentially of amino acids 1-322 of SEQ ID NO: 2, a native or biologically active $p33^{QIK}$, or a native or biologically active $p63^{Krs1}$. The antibodies differ in their structures and modes of action; a person of ordinary skill in the art would not envision one in view of the other. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

4. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

5. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-60, drawn to native, or biologically active mammalian p33^{QIK}; classified in Class 435, subclass 194.

II. Claims 1-60, drawn to native, or biologically active mammalian p63^{Krs1}; classified in Class 435, subclass 194.

III. Claims 1-12, 32, and 50-52, drawn to an isolated peptide (any of SEQ ID NOS: 3-76), and a polypeptide consisting essentially of amino acids 1-322 of SEQ ID NO: 2; classified in Class 530, subclasses 300 and 350.

IV. Claims 13-52, drawn to an antibody, antigen-binding fragments, compositions thereof, and a host cell capable of making the antibody as it reads on the an isolated peptide (any one of SEQ ID NOS: 3-76) or an isolated polypeptide consisting essentially of an amino acid sequence 1-322 of SEQ ID NO: 2; classified in Class 530, subclass 387.1;

V. Claims 13-52, drawn to an antibody, antigen-binding fragments, and compositions thereof as it reads on a native, or biologically-active mammalian p33^{QIK} peptide or polypeptide; classified in Class 530, subclass 388.26; classified in Class 424, subclass 146.1.

VI. Claims 13-52, drawn to an antibody, antigen-binding fragments, and compositions thereof as it reads on a native, or biologically-active mammalian p63^{Krs1} peptide or polypeptide; classified in Class 530, subclass 388.26; classified in Class 424, subclass 146.1.

VII. Claims 42-49, drawn to a composition comprising an isolated peptide (any one of SEQ ID NOS: 3-76) or an isolated polypeptide consisting essentially of an amino acid sequence 1-322 of SEQ ID NO: 2; classified in Class 4244, subclass 184.1.

VIII. Claims 42-49, drawn to a composition comprising a native, or biologically-active mammalian p33^{QIK} peptide or polypeptide; classified in Class 424, subclass 94.1.

IX. Claims 42-49, drawn to a composition comprising a native, or biologically-active mammalian p63^{Krs1} peptide or polypeptide; classified in Class 424, subclass 94.1.

X. Claims 53-56, drawn to a method of detecting mammalian p33^{QIK} peptide, polypeptide, or protein with an antibody that recognizes a peptide (any of SEQ ID NOS: 3-76) or a polypeptide (AA 1-322 of SEQ ID NO: 2); classified in Class 435, subclass 7.1.

XI. Claims 53-56, drawn to a method of detecting mammalian p33^{QIK} peptide, polypeptide, or protein with an antibody which recognizes a native, or biologically active mammalian p33^{QIK} peptide or polypeptide; classified in Class 435, subclass 7.1.

XII. Claims 53-56, drawn to a method of detecting mammalian $p63^{Krs1}$ peptide, polypeptide, or protein with an antibody which recognizes a peptide (any of SEQ ID NOS: 3-76) or a polypeptide (AA 1-322 of SEQ ID NO: 2); classified in Class 435, subclass 7.1.

XIII. Claims 53-56, drawn to a method of detecting mammalian $p63^{Krs1}$ peptide, polypeptide, or protein with an antibody which recognizes a native, or biologically active mammalian $p63^{Krs1}$ peptide or polypeptide; classified in Class 435, subclass 7.1.

XIV. Claims 57-58, drawn to a method of generating an immune or a T cell response in an animal as it reads on a peptide (any of SEQ ID NOS: 3-76) or a polypeptide (AA 1-322 of SEQ ID NO: 2); classified in Class 514, subclass 44; classified in Class 424, subclass 184.1.

XV. Claims 59-60, drawn to a method of inhibiting the biological activity of a $p33^{QIK}$ peptide or polypeptide in a cell as it reads on an antibody which recognizes a peptide (any of SEQ ID NOS: 3-76) or a polypeptide (AA 1-322 of SEQ ID NO: 2); classified in Class 424, subclass 130.1.

XVI. Claims 59-60, drawn to a method of inhibiting the biological activity of a $p33^{QIK}$ peptide or polypeptide in a cell as it reads on an antibody which recognizes a native, or biologically active mammalian $p33^{QIK}$ peptide or polypeptide; classified in Class 424, subclass 130.1.

XVII. Claims 59-60, drawn to a method of inhibiting the biological activity of a $p63^{Krs1}$ peptide or polypeptide in a cell as it reads on an antibody which recognizes a peptide (any of SEQ ID NOS: 3-76) or a polypeptide (AA 1-322 of SEQ ID NO: 2); classified in Class 424, subclass 130.1.

XVIII. Claims 59-60, drawn to a method of inhibiting the biological activity of a $p63^{Krs1}$ peptide or polypeptide in a cell as it reads on an antibody which recognizes a native, or biologically active mammalian $p63^{Krs1}$ peptide or polypeptide; classified in Class 424, subclass 130.1.

6. Groups I-IX are different products. Peptides, polypeptides, antibodies, compositions and fragments thereof, and kits containing compounds and compositions thereof differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

7. Groups X-XVIII are different methods. A method of detecting, and a method of generating an immune or T cell response, and a method of inhibiting differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

8. (Groups III and XIV), (Groups IV and X/XII/XV/XVII), (Groups V and XI/XVI), and (Groups VI and XIII/XVIII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the peptide/polypeptide of Group III could be used as an antigen to make antibodies in addition to the methods of detecting, methods of generating, and methods of inhibiting recited.

In the instant case the antibodies of Groups IV-VI can be used for affinity purification, in addition to the methods of detecting, methods of generating, and methods of inhibiting recited.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species Election

10. This application contains claims directed to the following patentably distinct species of the claimed Inventions III/IV/VII/X/XII/XIV/XV/XVII: wherein the peptide is:

One of the SEQ ID NOS: 3-76

These species are distinct because the structures of the peptides differ; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. In addition to the species set forth in SEQ ID NOS: 3-76, it is noted that the claims recite peptides of about 9-20/30/40/50/60/70 amino acids in length, recited in claims 1-6; as well as peptides of intermediate lengths, and peptide variants as disclosed on pages 9-30 of the instant specification.

Applicant is reminded to elect one ultimate species.

These species are distinct because the structures and modes of actions of the cell types differ; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.
Patent Examiner
Technology Center 1600
November 15, 2001

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
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4/16/01